EXHIBIT J

IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION

IN RE ETHICON, INC., PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION	:Master File NO. :2:21-MD-02327 : :MDL 2327
THIS DOCUMENT RELATES TO THE FOLLOWING CASE IN WAVE 2 OF MDL 200	: : :
PAMELA BAILEY AND HOUSTON BAILEY,	: :
Plaintiffs,	:JOSEPH R. GOODWIN :U.S. DISTRICT JUDGE
v.	: :
ETHICON, INC., et al.,	: :
Defendants.	:Case No. :2:12-CV-01700

June 6, 2016

Videotaped deposition of KONSTANTIN WALMSLEY, M.D., held at COURTYARD MARRIOTT WEST ORANGE, 8 Rooney Circle, West Orange, New Jersey, before Margaret M. Reihl, RPR, CCR, CRR, CLR and Notary Public, on the above date, commencing at 10:59 a.m.

A P P E A R A N C E S:

MOTLEY RICE LLC
BY: FRED THOMPSON, III, ESQUIRE
28 Bridgeside Boulevard
Mount Pleasant, South Carolina 29464
(843) 216-9118
fthompson@motleyrice.com
Representing Plaintiff

FRIDAY ELDREDGE & CLARK LLP
BY: WILLIAM MELL GRIFFIN, III, ESQUIRE
400 West Capitol Avenue
Suite 2000
Little Rock, Arkansas 72201
(501) 370-1515
griffin@fridayfirm.com
Representing Johnson & Johnson and Ethicon

I N D E X

– – –

E X H I B I T S

– – –

... KONSTANTIN WALMSLEY, M.D., having been duly sworn as a witness, was examined and testified as follows ...

BY MR. GRIFFIN:

Q. Dr. Walmsley, my name is Will Griffin. I represent Johnson & Johnson, and I'm here to ask you questions regarding Pamela Bailey.

Have you been hired in a case styled Pamela Bailey versus Ethicon to testify on behalf of Pamela Bailey?

A. I have.

Q. Okay. Could you give us your full name.

A. Konstantin Walmsley.

Q. And, Dr. Walmsley, where do you practice?

A. New Jersey.

Q. And you've been kind enough to tell me during an earlier deposition, you are a urologist, correct?

A. Yes, sir.

(Document marked for identification as Walmsley-Bailey Deposition Exhibit No. 1.)

BY MR. GRIFFIN:

Q. I'm going to show you what's marked as

Exhibit 1 to your deposition in this case, which is a Notice of Deposition.

Were you provided that?

A. I was.

Q. Did you bring the documents that were requested in that Notice of Deposition?

A. I have them, the majority of them electronically with me today.

Q. But have you brought me a thumb drive or anything like that?

A. I have not.

Q. Okay. Have you brought any of them in paper form?

A. I have not.

Q. Okay. And the only thing -- as I understand it, the only thing you have brought with you is your report that's in paper form; is that true?

A. In paper form, this is true, yes.

Q. Have you even brought your examination notes?

A. I have them electronically.

Q. Okay.

MR. GRIFFIN: We'll mark this as Exhibit 2.

(Document marked for identification as Walmsley-Bailey Deposition Exhibit No. 2.)

BY MR. GRIFFIN:

Q. I'm going to show you what was marked as Exhibit 2 and make sure I haven't drawn all over it.

I'm going to show you what's marked as Exhibit 2. Could you identify that?

A. Yes. This is a Rule 26 expert report on Pamela Bailey.

Q. Did you -- is that your report?

A. Yes, sir.

Q. Did you draft it?

A. I did.

(Document marked for identification as Walmsley-Bailey Deposition Exhibit No. 3.)

BY MR. GRIFFIN:

Q. Okay. I'm going to show you Exhibit 3 and ask if you can identify that?

A. This is my independent medical examination of Pamela Bailey dated May 3rd, 2016.

Q. Okay. Dr. Walmsley your report indicates the various medical records you reviewed. Did you review any depositions?

A. Yes, I did.

Q. What depositions?

A. I believe I reviewed the deposition -- not believe -- I reviewed the deposition of Dr. Adam and Ms. Bailey.

Q. Did you review Dr. Perlow's deposition?

A. I don't recall reviewing Dr. Perlow's deposition. It may have been sent to me. I don't believe I had the time to review it.

Q. So, as we sit here today, you do not have any knowledge of what Dr. Perlow did know or did not know regarding risks and complications of pelvic mesh procedures?

A. I do not.

Q. So you do not intend to offer an opinion that Dr. Perlow was unaware of the potential risk and complications of the TVT procedure, true?

A. The only shortcoming, once again, to his informed consent was based on his knowledge or lack thereof based on the IFU.

Q. But an IFU doesn't include all the risks -- your opinion is that the IFU doesn't include all the risks that would allow a doctor to give adequate informed consent?

A. Yes, this report speaks to that.

Q. Okay. And I guess the basis of that is that a physician has to know of the potential risks and complications to give an adequate informed consent, correct?

A. That's correct.

Q. And you would agree physicians may become aware of risk and complications of a TVT procedure by means other than an IFU, true?

A. This is in part true.

Q. They might obtain it from their training, true?

A. Yes.

Q. Experience, true?

A. Yes.

Q. Literature, true?

A. Correct.

Q. Colleagues?

A. Yes.

Q. Seminars?

A. True.

Q. And from what I understand from your earlier answers, you have no knowledge of what Dr. Perlow had obtained in terms of knowledge from his training, experience, literature, discussions with

colleagues, seminars, things of that sort, correct?

A. Not from my evaluation of the medical records, no.

Q. And so, as we sit here today, you are not offering an opinion that Dr. Perlow did not have sufficient knowledge of the risk and complications of the TVT procedures to advise the patient, correct?

MR. THOMPSON: Object to the form.

THE WITNESS: I am offering that opinion.

BY MR. GRIFFIN:

Q. And you are offering that opinion despite the fact that you have absolutely no knowledge of what information Dr. Perlow had in his possession at the time of the surgery of Ms. Bailey that he may have obtained from his training, experience, literature, discussions with colleagues and seminars, correct?

A. Well, I do have knowledge of one of the elements required from the informed consent that Dr. Perlow had at the time of that surgery.

Q. That was the IFU?

A. That's correct.

Q. But that wasn't my question.

You have absolutely no knowledge of what

information Dr. Perlow had in his possession at the time of the surgery of Ms. Bailey that he may have obtained from his training, experience, literature, discussions with colleagues and seminars, correct?

A. Well, I would disagree with that comment.

Q. Did you read his deposition to attempt to obtain that knowledge?

A. I have not read his deposition.

Q. So you do not know what Dr. Perlow knew or didn't know at the time of Ms. Bailey's procedure, true?

A. I'm not aware of what he shared in his deposition regarding what he knew or didn't know.

Q. And if you're not aware of that, then you don't know what he knew in terms of risk and complications at the time of the surgery of Ms. Bailey, correct?

A. That's not entirely true, but in part true.

Q. Well, the only thing that you're aware of is the IFU, and you don't even know whether he reviewed the IFU before he performed this procedure, true?

A. I would assume he would have reviewed it, but it's possible he did not review it.

Q. So the answer is you don't know, true?

A. I don't know if he reviewed the IFU.

Q. Do you know whether Dr. Perlow addressed the issue of whether additional information in the IFU would have changed his mind in recommending the procedure?

A. I'm not aware of that.

Q. In your -- you have a Case Specific Opinion 1. Let me ask you this, let me go to your General Opinion 2 since it's in this report.

A. Sure.

Q. You do agree that there are risks of dyspareunia with your autologous fascial slings, correct?

A. Yes.

Q. So even the, quote, safer alternative designs that you say existed in 2001 carried the risk of dyspareunia, true?

A. Yes.

Q. And there's no way for you to predict in advance which particular patient may have dyspareunia and which may not, correct?

A. Not entirely true.
Q. What?
A. Not entirely true.
Q. Fill me in.
A. Well, I mean, if patients have conditions that might otherwise increase their risk of dyspareunia, you can sometimes counsel patients that they might have a higher risk of dyspareunia because of prior surgery, et cetera.
Q. I get what you're saying, but the point is you don't know which patients are going to develop dyspareunia and which patients are not, correct?
A. Not with 100% accuracy, no.
Q. Have you had patients develop dyspareunia?
A. After surgery you mean?
Q. Yes.
A. I have.
Q. In what kind of procedures?
A. Certainly after sling surgery.
Q. Autologous?
A. Rarely, but yes.
Q. So the autologous fascial slings, you have personal experience with patients who have

developed dyspareunia, correct?

A. I have.

Q. And you have had patients with mesh procedures who have developed dyspareunia as well, correct?

A. That's correct.

Q. As I understand it, you do not use the Ethicon products, though, correct?

A. Not in my private practice.

Q. You use the Bard Coloplast and AMS devices?

A. The answer to that is yes.

Q. And using those devices you have had patients develop dyspareunia as well?

A. I have.

Q. Your Case Specific Opinion Number 1 in the Bailey case, you indicate that recognized causes of sling erosion include and number one is surgical error in implantation technique; is that correct?

A. Yes.

Q. And what would the surgical error be? Would that be making it taut rather than tension free?

A. That might be one of the ways.

Q. So if the surgeon made the TVT sling

taut rather than leaving it tension free, that would be -- cause the potential for vaginal sling erosion?

A. That could happen.

Q. Do you know what Dr. Perlow's complication rate was in terms of over tensioning these devices?

A. I'm not aware of that.

Q. What is the complication rate for over tensioning a TVT?

A. Well, it depends on where you're trying to extract that information, so it's very hard to answer that question with much accuracy.

Q. What's your understanding, generally?

A. Probably on the order of single digit percentage points.

Q. Something less than 10%?

A. Yeah, I would conjecture that's about right.

Q. If a physician is having double that, then the physician may have -- may be having a problem with figuring out how to implant the device, correct?

A. Possibly.

Q. Well, not just possibly, more likely than not, correct?

MR. THOMPSON: Object to the form.

THE WITNESS: To some degree, you know, the variable could also be patients as well and also might also be related to how one defines over tensioning.

BY MR. GRIFFIN:

Q. What would it tell you if Dr. Perlow testified that he had a problem with over tensioning these devices?

A. That would tell me that perhaps he had a learning curve.

Q. If you're over tensioning the device, you're pulling it taut, correct?

A. Possibly.

Q. What you want to do is leave it tension free, correct?

A. That's the goal of the procedure, yes.

Q. Did you make a determination as to whether Dr. Perlow did, I guess, over tension the device?

A. I did formulate an opinion regarding that.

Q. So you have the Case Specific Opinion Number 1 that there was vaginal sling erosion which was

caused by shrinkage of the mesh, true?

A. Retraction and shrinkage of the mesh.

Q. Right. And in coming to that opinion, you ruled out surgical error on implantation, correct?

A. Correct.

Q. And the way you ruled that out was how?

A. Dr. Perlow's operative dictation and Mrs. Bailey's postoperative treatment course.

Q. So there's two things there, one would be his operative report?

A. Correct.

Q. And in the operative report it indicates he left it tension free, true?

A. Yes.

Q. In other words, he didn't pull it taut, correct?

A. He specifically used a spacer, a pair of scissors as a spacer to ensure tension-free placement.

Q. And if you do that, you're not going to pull it taut, right?

A. Should not.

Q. And if you're pulling the sling taut, you run the risk of over tensioning the device, correct?

A. That may be one reason to do that -- or one way to do that.

Q. And your understanding was that Dr. Perlow did not do that, correct?

A. In the setting of using a spacer, such as a Metzenbaum scissors, it's hard even in the setting of a taut pull to set it too tight.

Q. I'm going to show you Bailey WellStar Windy Hill Hospital, Page 7 of the MDR.

Does Dr. Perlow indicate that the vaginal tape was pulled tight, that it was taut, so that it would suspend the urethra?

A. It states, vaginal tape was pulled taut so that it would suspend the urethra, and Metzenbaum scissors was used as a spacer.

Q. That's not what you would expect to find in operative dictation for placement of a TVT, correct?

A. Possibly, but not necessarily.

Q. You've never seen a physician indicate that they pulled it taut, have you?

A. I don't know if I would say that necessarily.

Q. Can you remember a single case you've reviewed or where you, yourself have done it where

you've used the words pulled the TVT or the similar device taut?

A. Well, when one is setting a TVT sling, you're removing spacers, plastic sheaths that are around the sling. Oftentimes there is a tendency when removing those sleeves to create some tension. However, if you have a spacer in place, that more or less protects that pulling of sheath out phenomenon from over tensioning.

So even though his operative note memorialized a taut pull of the sling, the presence of the scissors as a spacer should ensure a tension-free placement.

Q. Doctor, if he says he pulled it taut in the operative report and he indicated he had a 20% complication rate of over tensioning these devices, does that tell you that there's the potential in this particular case, Pamela Bailey's case, that the TVT was initially over tensioned?

MR. THOMPSON: Object to the form.

THE WITNESS: I would disagree with that.

BY MR. GRIFFIN:

Q. And is that because of your finding that

she did not indicate any problems of emptying her bladder initially after the surgery?

A. Correct.

Q. That would be the only reason, correct?

A. That would be my main reason.

Q. You can't think of any other reason, as we sit here, true?

A. Well, the only other reason would be the use of a spacer.

Q. If she did have symptoms of trouble emptying her bladder from the time of the surgery, that would be indicative of the sling being placed too tightly, correct?

A. Not necessary.

Q. Didn't you just tell me that?

A. Well, it depends on the chronology with which her obstructive symptoms presented.

Q. Okay. If she had the symptoms of inability to empty her bladder from the time of the surgery itself, that would be indicative that the sling was possibly placed too tightly, correct?

A. That would be a possibility.

(Document marked for identification as Walmsley-Bailey Deposition Exhibit No. 4.)

BY MR. GRIFFIN:

Q. Let me show you Exhibit 4 and ask you if she told Dr. Osterloh that she had had trouble emptying her bladder from the time of her surgery?

A. That's what's stated on this note.

Q. And if that is, in fact, true, that is a potential sign that the midurethral sling placed by Dr. Perlow was placed too tight or in a nontension free manner, correct?

A. Once again, I would disagree with that strictly on the basis of a sling in my practice that's been over tensioned too tightly will literally present with retention almost immediately to the point that a patient requires catheterization to empty her bladder.

One thing that can happen following sling surgery, even if it's placed in a tension-free fashion, is that patients can suffer symptoms of incomplete emptying that are more related on swelling and inflammation post sling implantation that then can resolve over time. The other possibility is that a sling that's placed in a tension-free fashion can, through the formation of scar plate or contraction, develop an obstructive symptomatology.

So the presence of a note ten years

after the sling that speaks to that raises the possibility, of course, but doesn't necessarily rule that in with the highest degree of certainty, only insofar as this patient did not require catheter or catheterization following her surgery.

Q. So it raises the possibility -- the patient's statement that she had trouble emptying her bladder after her TVT procedure raises the possibility that the device was placed too tautly; is that correct?

MR. THOMPSON: Object to the form.

THE WITNESS: I'm not offering that opinion, only because if that were the case, she would literally require a catheter to drain her bladder. That's typically the complication of over tensioning is urinary retention requiring a catheter, that in 2016, for example, typically requires -- the standard of care calls for a revision of the sling within a few weeks because of that phenomenon.

So maybe I'm defining over tensioning in a different way. Obviously, the sling did ultimately become too tight because of the findings discovered later on. That being said, the fact that there's the description of taut

in an operative dictation to me is put in the proper context of a spacer being used doesn't suggest over tensioning.

Q. Okay. The one possibility for a patient experiencing the inability to completely void or empty the bladder is the fact that a TVT may have been placed in too tight a manner, correct?

A. Depending upon the chronology with which you're posing that question, that's possible.

Q. Okay. Not every TVT that is placed too tightly requires the placement of a catheter, correct?

A. That would be incorrect.

Q. Are you saying every TVT that is placed too tightly requires the use of a catheter?

A. Almost invariably, yes.

Q. Some patients simply have the inability to void or feel like they have completely voided, true?

A. Not true to my -- no, I would disagree with that.

Q. You don't have that understanding based on the literature you've reviewed, correct?

A. Based on the literature that I reviewed and my own clinical experience, over tensioning of the sling is a phenomenon that presents with the immediate

need for a catheter, a catheter to drain one's bladder and sometimes can be related to a voiding dysfunction that you see immediately following surgery as well.

Q. You indicate that there was mesh erosion, not mesh exposure. Do you make a distinction between those two terms?

A. I think of them along a continuum.

Q. Okay.

A. In other words, first off, an erosion event can include eroding into spaces or organs other than the vagina. Whereas an extrusion event really is an erosive event into the vaginal space. I think of an extrusion as a mini vaginal erosion. That's how I would define it, an exposure being another means of defining an erosion of mesh into the vaginal space. So I guess extrusion and exposure are subsets of an erosion condition.

Q. Did you read Dr. Adam's testimony on that?

A. I did.

Q. Okay. Did Dr. Adam remove the mesh in this particular case?

A. Partial mesh removal.

Q. Did he find evidence of degradation of

the mesh?

A. I don't recall seeing that.

Q. You don't recall seeing that, or did he not find that?

A. I don't recall him mentioning that he found that.

Q. You know he was asked that specifically, true?

A. He was.

Q. And he said he did not see that, true?

A. Well, that's -- yes.

Q. I just want to make sure you're not recalling it versus --

A. That's fair.

Q. That's what he said?

A. Yeah.

Q. You would agree that Dr. Adam did not find evidence of degradation, curling, fraying or roping of the mesh when he took out a portion of the mesh, true?

A. This is true.

Q. You make the statement or you give the opinion that Dr. Perlow placed it tension free, correct?

A. That's correct.

Q. You have no way of knowing, in fact, whether he did or didn't, other than the statement that he used the Metzenbaum scissors and your belief that she would have needed to be catheterized, correct?

A. I believe I also have a way of knowing in light of my having performed an IME on this patient as well.

Q. Before we get to the IME, you made the statement that the mesh was placed tension free without reading the deposition of Dr. Perlow, true?

A. That's correct.

Q. And when you made the statement, in your opinion, which I think is Exhibit 2; is that right?

A. Yes, sir.

Q. You were unaware of what Dr. Perlow's complication rate was with over tensioning of devices and what his testimony was regarding over tensioning of devices, correct?

A. That's correct.

Q. Did Dr. Adam testify that he found that the mesh had shrunk?

A. I don't believe he used that language.

Q. Did he use any language that would be a

synonym for shrunk?

A. I think his medical records speak towards a significant compression of the urethra, which is consistent with shrinkage.

Q. The compression of the urethra could happen as a result of scarring, correct?

A. True.

Q. It could happen as a result of over tensioning, correct?

A. Theoretically.

Q. And you contend that it could happen as a result of the mesh itself shrinking, correct?

A. That's correct.

Q. Do you know whether it occurred in this case due to mesh contracting or scarring?

A. I believe it was probably both of those issues.

Q. Do you know -- I assume you don't know the percentages of each, correct?

A. I think it would be difficult to put forth an opinion on that.

Q. It may be all scarring, true?

A. Possibly.

Q. And does scarring result -- is there

scarring with any SUI procedure, surgical procedure?

A. To some degree.

Q. In your Case Specific Opinion Number 2, you indicate the various causes of dyspareunia that you rule in and rule out, true?

A. Yes.

Q. I want to ask you, what is your understanding of when the dyspareunia was worse, after Dr. Perlow's surgery, after Dr. Adam's surgery, or has it remained the same?

A. When I interviewed the patient, she started having dyspareunia about three months after her 2001 surgery.

Q. Has it remained the same or was it better or worse as a result of the surgery by Dr. Adam?

A. Dr. Adam's surgery was not -- certainly not curative of the problem, and I'm not convinced it changed very much with it.

Q. How often were they having sex before -- or after Dr. Perlow's surgery? Was it your understanding they were unable to or could not?

A. I asked her that question specifically when I examined her, and she claimed that she used to be sexually active every day. When I examined -- when

I discussed this with her in April -- pardon me -- in May of 2016, she described being sexually active every three to four months with pain.

Q. Do you know how often she was having it after Dr. Perlow's surgery before Dr. Adam's surgery?

A. Somewhere between three to four times a year and every day. I don't recall the exact amount.

Q. That's a pretty big gap.

A. I know it is. I apologize.

Q. Was it your understanding after Dr. Perlow's surgery, she was not sexually active due to dyspareunia?

A. Well, I do recall that, yes.

Q. She certainly was not having sex two to three times a week after Dr. Perlow's surgery, true?

A. No, that's true.

Q. Because if she was having sex two to three times a week after Dr. Perlow's surgery, that's inconsistent with dyspareunia, correct?

MR. THOMPSON: Object to the form.

THE WITNESS: I'm not sure if I understand that question.

BY MR. GRIFFIN:

Q. If she was having sex two to three times

a week after Dr. Perlow's surgery, that's inconsistent with severe dyspareunia, correct?

A. Well, it's a little bit of a different question than you posed before in terms of the use of the word severe, and I guess I would offer an opinion that one can still be sexually active and have dyspareunia. I mean, in other words, in having dyspareunia doesn't mean I cannot have sex, it just means one has sex and has discomfort doing so.

Q. Right. And she indicated to you she was having it three to four times a year, correct?

A. In 2016, that's what she told me.

Q. Which would be severe dyspareunia, as far as your understanding, true, or a lack of desire, I guess?

A. I think it would be, you know, possibly consistent with dyspareunia, yes.

Q. Okay. Two to three times a week is not consistent with your experience with patients claiming dyspareunia, correct?

A. Possibly, but not necessarily.

Q. Based on your experience, patients who are having dyspareunia are not having sex two to three times a week, correct?

A. If it were severe, that would be a surprise to me.

Q. And she had severe dyspareunia, based upon what she told you, true?

A. Well, in 2016 she was having severe dyspareunia and made fairly descriptive comments regarding what it was like.

Q. Right, and she's told you that she had had dyspareunia all the way back to Dr. Perlow's surgery, true?

A. Starting about three months after Dr. Perlow's surgery, correct.

Q. And it had been severe the entire time, true?

A. I don't recall her using the word severe, but suffice it to say, I know that she had had it ever since that surgery.

Q. Well, the description she gave you would equal severe. She may not have used that word severe, but the description she gave you, you would consider that severe dyspareunia back to the time Dr. Perlow was treating the patient, true?

MR. THOMPSON: Object to the form.

THE WITNESS: I'm not sure I could

answer that question with a great deal of confidence.

BY MR. GRIFFIN:

Q. But your understanding was three to four times a year, basically, since Dr. Perlow's surgery, true?

A. No. When I asked her that question, that was really more of a question over the last couple of years, so I didn't ask her specifically, you know, how often she was having sex, let's say, in 2002 or 2006, so forth. I know it was an ongoing complaint, obviously.

Q. Right.

Do you have patients with severe dyspareunia having sex two and three times a week with their spouse?

A. Actually, I do. I'm embarrassed to bring this up, but it's not vaginal intercourse, necessarily.

Q. I'm talking about vaginal intercourse, sexual intercourse.

A. I do not have patients in my practice with severe dyspareunia that have penetrating intercourse two to three times a week, unless their

husband maybe is -- I mean, there are instances in which I have patients with severe dyspareunia that still have sex.

Q. Sexual abuse type situations almost, correct?

A. No. It's, you know, more borne out of a patient's interest in keeping their husband fulfilled, and, I mean, I have patients that suffer to have sex so that their husband won't leave them. I mean, this is the truth.

Q. Tell me after Dr. Adam did his surgery, has there been any evidence of mesh exposure?

A. No, sir.

Q. Did you see any evidence of mesh exposure when you examined the patient, whether you call it exposure or extrusion?

A. I did not.

Q. You indicate in your report that you documented tenderness in the right periurethral area?

A. Yes.

Q. And your report indicates "tenderness along right periurethral area (? mesh vs. scar)."

Did I read that correctly?

A. That's correct.

Q. Is that because you don't know whether that is due to a scar or due to mesh?

A. I think it may be somewhat similar to a discourse that you and I had had prior regarding palpating scar tissue and not being able to determine if there might be some mesh underneath the scar tissue. There's no erosion, exposure, extrusion, et cetera, but there is a palpable thickening of the tissue that might have mesh underneath it.

Q. But you don't know whether there's mesh at that site, correct?

A. Correct.

Q. So the tenderness along the right periurethral area may be caused by the scar itself, correct?

A. You know as an indirect consequence of her surgeries, yes.

Q. And it could be as a result of the initial scar itself, correct?

A. That's hard to answer that question having not examined her between 2001 and 2005. It's a possibility.

Q. Well, she actually had what she described as dyspareunia before there was ever exposure

of the mesh, correct?

A. This is true.

Q. Okay. Which would give an indication that the scar itself from the placement of the mesh may have been the potential cause for her dyspareunia, correct?

A. Possibly.

Q. And that is, of course, a complication of placement of a TVT or placement of a autologous fascial graft, correct?

A. You are speaking of just the generalized presence of dyspareunia?

Q. The scar, a scar can cause that?

A. Any scar can cause that.

Q. And I guess when you place an autologous fascial sling, you have to make an incision in the vagina as well, correct?

A. That's correct.

Q. And that scar can lead potentially to dyspareunia, correct?

A. If it's located in the midline, that would be plausible.

Q. Do you ever locate them in the midline?

A. On occasion.

Q. Do you have patients that you have implanted autologous fascial slings in who have pain from the scar, dyspareunia that you attribute to the scar from the placement of the fascial sling?

A. This can happen in uncommon instances, yes.

Q. Do you have patients who that has happened to?

A. One or two, I do.

Q. You indicated that you excluded pelvic floor dysfunction. What did you mean by pelvic floor dysfunction?

A. Pelvic floor dysfunction usually speaks to issues such as pelvic floor muscle spasm or levator spasm, as it's sometimes called. This can typically be diagnosed not only through history taking but through a physical exam where you can actually document tightness or spasm of the levator muscles during an examination.

Q. Did you do that in your examination?

A. I did.

Q. Is that documented in your record?

A. As part of my examination of the female genitalia, that's something I typically do. It's not something that's present, I don't necessarily write no

levator spasm or things to that nature.

Q. Did you write anything regarding that test?

A. It's just part of my vaginal exam when I'm doing a bimanual exam to assess for the presence or absence of that, and, typically, because this is a template, the template doesn't include absent levator spasm. It's usually something that's provided if the finding is there.

Q. Did you document that anywhere in this report, the absence of levator spasm?

A. Well, I guess what I didn't document was the presence of levator spasm, thereby implying that there was no levator spasm.

Q. Well, in your examinations you specifically make references to things you don't find, correct?

A. I specifically make references using an electronic health record generated template.

Q. Well, you specifically state that you found tenderness, right?

A. Correct.

Q. You stated that you found no masses, atrophy or lesions, correct?

A. That's correct.

Q. You state you found no urethral discharge or mass, true?

A. In fact, one thing that's very helpful with electronic health resources is when there is a specific pertinent, positive finding, it's bolded, as you can see, relating to the tenderness comment.

Q. Is there anything in here that says no levator spasm?

A. There was none found during my exam, so I didn't provide that, given the fact that it wasn't part of the template.

Q. So it just depends on what's in the template as to what ends up in the report?

A. No, that's not true. What ends up in the template is generated by the electronic health resource, but in my examination, if I find something that's relevant and pertinent, I'll add that.

Q. Well, you specifically said that it was relevant and pertinent in the opinions you were giving in this case that there was no pelvic floor dysfunction, correct?

A. There is no pelvic floor dysfunction in any of the medical records, including my IME, that's

correct.

Q. And you state that --

A. In fact -- I'm sorry.

Q. Go ahead.

A. I was just going to say Dr. Adam made mention of the fact that in his examination in 2005, her levator ani were normal.

Q. And you say there's an absence of documented tenderness to the pelvic floor musculature by multiple consultants, correct?

A. That's correct.

Q. Who are these multiple consultants?

A. Dr. Adam, Dr. Sward.

Q. Dr. Adam, 2005?

A. Yeah. Dr. Sward in 2004. Myself. There's no mention in Dr. Osterloh, if I'm saying her name right, in her findings of such.

Q. She doesn't do a pelvic exam, does she?

A. This is true.

Q. Has a single pelvic exam been done on this patient since 2005 until the time you saw her in 2016?

A. I have no evidence of such.

Q. So as far as you can tell from your

review of the records, for 11 years she did not have a single vaginal examination?

A. Not that I have seen, no.

Q. Did you see any complaints to any physicians from 2005 to the time you saw her complaining about dyspareunia?

A. I did not.

Q. Did you find any complaints of dyspareunia that occurred before she -- from 2005 until after she filed this lawsuit?

A. I did not.

Q. Does she suffer from incontinence currently?

A. Not currently, no.

Q. Did she have incontinence before the procedure performed by Dr. Perlow?

A. Yes, sir, she did.

Q. So would it be your conclusion that the TVT has corrected her incontinence?

A. No.

Q. And that's because?

A. Well, she's required multiple surgeries since her TVT to resolve her incontinence.

Q. What are the multiple surgeries?

A. Well, firstly, she had collagen injections following her SUI surgery, the TVT-O placement.

Q. Those had a temporary effect, correct?

A. That had a temporary benefit.

Q. Okay. That's not surgery, is it? I guess it depends on your definition.

A. Well, it depends how one defines it. It's a minor surgery or a minor procedure, if you will.

Q. Okay.

A. Sometimes those are done in the office, sometimes those are done in a hospital setting, so I think it's hard to say whether you call it surgery or otherwise.

Q. The only other true surgery was the excision of the mesh, correct?

A. Yeah, and along those lines, when she originally presented to Dr. Adam in February of 2005, her urinary incontinence was ongoing.

Q. But by the time you see her, there is no urinary incontinence?

A. This is true.

Q. Did it self-heal?

A. Following Dr. Adam's surgery, her

incontinence resolved. When she last saw Dr. Adam, July 14, 2005, a little over four months postoperatively, she was still leaking occasionally. By the time I saw her, she was no longer having incontinence.

Q. So Dr. Adam removed a portion of the sling?

A. That's correct.

Q. And by removing a portion of the sling, the patient -- it resolved the patient's incontinence?

A. Ultimately, that surgery proved to be successful in that regard, yes.

Q. But the TVT, a portion of it remains in place, correct?

A. That's correct.

Q. So the remaining portion is what is I guess taking care of her incontinence?

A. Not exactly, no.

Q. What is?

A. Well, one of the premises around which mesh-based slings work is their ability to create an inflammatory response and scar tissue. One of the reasons you can see mesh-related complications is in part related to the inflammation and scar tissue that

results.

If you can imagine, at least when I examined Ms. Bailey, what she had was one piece of mesh on the right side, one piece of mesh on the left side and then a scar bridge between those two pieces of mesh. So really her continent mechanism is not only in part related to the mesh but the very inflammatory response and scar tissue formation that one expects from the mesh. That's one of the reasons you don't have to suture mesh in place. It self-affixes by virtue of the inflammatory response it creates.

Q. So the effect of the TVT in causing scar tissue is what has solved her incontinence, would that be a fair way to say it?

MR. THOMPSON: Object to the form.

THE WITNESS: I think it's a combination of both. In other words, in instances where you removed more of the mesh, the scar tissue doesn't necessarily provide all of the support needed to provide continence. In this instance, obviously, whether it's scar tissue or the actual mesh itself, it succeeded in doing so.

BY MR. GRIFFIN:

Q. So you believe that there's a combination of the mesh and the scar tissue that was caused by the implantation of the mesh that is -- has cured her incontinence; would that be a fair way to say it?

MR. THOMPSON: Object to the form.

THE WITNESS: I would add to that and say as well as the additional surgery scarring that has done that, yes.

BY MR. GRIFFIN:

Q. So the dyspareunia which she currently has could be caused by the incisional scar alone, correct?

A. Not correct. Not based on my evaluation and examination where -- well, couple of points to make. First off, the majority of her tenderness that she described as being what she felt when she had dyspareunia is on the right side of her vaginal space so that periurethral space, number one.

Q. Was there an incision in that area where the mesh was removed?

A. Not necessarily, but possibly. I think to really formulate a better opinion on that, I really have to relook at Dr. Adam's operative note to make a

comment to that effect, and the reason I say that is because typically in the setting of a partial mesh excision, one will typically make a midline incision and then access the eroded mesh from that midline incision by dissecting underneath the vaginal space to access the mesh.

And, as I sit here today, I'm not specifically recalling if Dr. Adam made that approach towards removing the mesh, in other words, a midline incision, or whether he incised transversely, if you will, under the mesh to deliver it, in which case your question and your theory would be plausible.

Q. Did you indicate that the patient currently has incomplete bladder emptying?

A. My comment made was that she has to strain to urinate.

Q. So that's a voiding dysfunction, in essence, correct?

A. Yes, sir.

Q. Did you do any post void residual testing on her?

A. I did not.

Q. And what would you be looking for in that kind of testing?

A. Well, there are two ways to assess for incomplete bladder emptying from an objective standpoint. Certainly one of the best is to scan the bladder after urination and assess their post void residual. Oftentimes you can get a sense of their emptying ability on the basis of a physical examination, where you palpate over the suprapubic area in the location of the bladder to sense, number one, if you can palpate their bladder and/or, number two, if they feel a desire to urinate upon that palpation.

Q. Did you do that?

A. I did.

Q. What did you find?

A. I didn't clinically suspect her of having incomplete bladder emptying based on my physical examination in the absence of a bladder scan.

Q. Was that inconsistent or consistent with her continued voiding dysfunction?

A. Well, I think that you have to take into account that the diagnosis of incomplete bladder emptying can be a subjective one as well as an objective one. Certainly, the fact that she is straining to void suggests that she has some sort of bladder outlet obstruction. Whether that's manifesting

with an actual objective finding of elevated post void residuals or a true objective incomplete bladder emptying doesn't necessarily mean a patient can't have that feeling.

Q. When was the last post void residuals done on this patient?

A. From my recollection, July 14th, 2005.

Q. And what were the results of that?

A. It was 10 CCs.

Q. That's pretty small, isn't it?

A. Yes.

Q. That would not support incomplete bladder emptying, correct, objectively?

A. I would agree with that.

Q. So that would be inconsistent with voiding dysfunction?

A. Well, I think the fact that someone is complaining about having that, yet doesn't have that, to me is part of the syndrome of voiding dysfunction.

Q. She has complained specifically of incomplete bladder emptying, correct?

A. Having that feeling, yes.

Q. All objective testing that's been done by you and by Dr. Adam in 2005 doesn't support that,

true?

A. That's correct.

MR. GRIFFIN: Take a break for a minute.

(Brief recess taken at 12:03 p.m.)

(Deposition resumes at 12:09 p.m.)

BY MR. GRIFFIN:

Q. Dr. Walmsley, you stated that you felt it was an induration or was it just tenderness in the right periurethral area?

A. Well, it was both based on the comment made following that question, mesh versus scar.

Q. Okay. Is it your understanding where you felt that tenderness, that was where the mesh was excised?

A. Possibly, yes.

Q. So necessarily an incision would have been made where the mesh was excised, correct?

A. Well, as I alluded to before, sometimes the surgical technique involves making a midline incision and then tracking underneath the vaginal lining to the area of the mesh erosion. Other instances involve making incision adjacent to the mesh erosion. Suffice it to say, the area of her mesh erosion and subsequent removal was certainly in the

area where my examination would indicate that that surgery was done.

Q. And that one of the ways you would remove that mesh is to make your incision just proximal to the area where the mesh was exposed, correct?

A. Yeah, and that's my understanding as to what Dr. Adam did.

Q. Okay. And that would not be midline based upon your findings in 2016, correct?

A. Neither based on my findings or the location of the actual erosion based on Dr. Adam's records.

Q. So there was an actual incision and scar tissue in that area probably from the surgery itself, correct?

A. The incision I think was proximal to that area, but close to it.

Q. And your point in your examination is that that tender area may be the scarring itself from the incision or scarring from mesh, correct?

A. No, that was not my insinuation from the exam. My insinuation from the exam was that that tenderness could be relating to the mesh itself or to scar tissue. I wasn't attributing it to the incision

per se.

Q. Well, the incision created scar tissue itself, correct?

A. Yes, to some degree this is true, yes.

Q. And that scar tissue could be causing the tenderness and dyspareunia, correct?

A. I guess for the purposes of specificity, are you talking about the incision from Dr. Adam's procedure or the incision from Dr. Perlow's procedure?

Q. Well, it could be the incision from Dr. Adam's procedure, correct?

A. Well, the only reason I have to take issue with that is because when Dr. Adam examined her prior to his surgery, he was able to elicit tenderness in that area prior to his own incision.

Q. Right.

There was mesh exposure at that time, true, when Dr. Adam saw the patient?

A. Yes, sir.

Q. And there was tenderness in the area of the mesh exposure, true?

A. True.

Q. And Dr. Adam -- and up until that point in time, the patient was having sex two to three times

a week, correct?

A. That is true.

Q. So up until the time Dr. Adam operated on this patient, she was having sex with her husband two to three times a week, true?

A. Yes.

Q. And then after Dr. Adam operated on the patient, how often was she able to have sex?

A. To my mind, less frequently than that.

Q. And is it your understanding from reading the fact witness depositions that everything went downhill as far as their sex lives after Dr. Adam's procedure?

A. I wouldn't read it as such, no.

Q. How did you read it?

A. Well, I felt like the problem started after her sling surgery was done and were not ameliorated by Dr. Adam's procedure.

Q. So you did not have the understanding that everything went downhill after Dr. Adam's procedure as far as their sex life?

A. I think things worsened after that procedure, but they weren't in tip-top shape going into that procedure either.

Q. Well, they were in pretty good shape if she was having sex two to three times a week, weren't they?

A. Well, once again, I think you have to qualify the enjoyment of that process. I mean, for better or for worse, as my understanding goes, she was having discomfort during sex but was doing so regardless.

Q. Where did you read that?

A. This is based on my discussions with her.

Q. And that's what she told you, she was having sex despite being in pain?

A. She used words -- both her and her husband expressing feelings of guilt to the point that he felt guilty about doing it now because of the fact that he knew how uncomfortable it was for her, but that flavor was insinuated to their sex life after the TVT-O sling was placed as well, that it wasn't necessarily a comfortable act for her.

Q. Did you read Houston Bailey's deposition, her husband's deposition?

A. I did not.

Q. So when you offered these opinions

regarding when the dyspareunia was worse, when the dyspareunia was better, you had not had the opportunity to review Houston Bailey's deposition?

A. I hadn't read his.

Q. You had not?

A. I had not read that deposition.

Q. As I understand it, if a patient has exposure of the mesh into the vagina, her partner may feel a scratching sensation or a prickling sensation, correct?

A. That's described often, yes.

Q. Okay. When you saw the patient in 2015, did they have exposure of the mesh?

A. It was in 2016.

Q. 2016, there was no exposure of mesh?

A. I did not appreciate such.

Q. You did not feel a slicing or a cutting of your finger or anything of that sort when you conducted your manual examination, correct?

A. I just felt palpable scar.

Q. There was nothing that would be causing a scratching or cutting or scraping of the penis, correct?

A. Possibly scar tissue, but, certainly, I

wouldn't attribute that to a mesh exposure phenomenon.

Q. And you didn't feel that type of scratching sensation when you conducted your examination of the patient manually, correct?

A. Well, using my gloved finger I did not, no.

Q. Are you currently using midurethral sling procedures?

A. I am.

Q. Do you read the IFU before you do every midurethral sling procedure?

A. I try to stay up-to-date with the IFUs, yes.

Q. Do you read the IFU every time you do a midurethral sling procedure?

A. I tend to look at the IFUs about once a year, so if you're saying before each individual procedure do I pull out the IFU and look at it, the answer to that would be no. Sometimes if there's turnover time, you've got nothing better to do, you might take a glimpse at it and just make sure nothing has really changed.

Q. And in doing your informed consent with the patient, you do not rely only on the IFU, do you?

A. I use it as part of my informed consent, that's true.

Q. Right. And what are the other things you use as part of your informed consent?

A. My training, as it relates to transvaginal mesh, some of the workshops I have attended.

Q. What you've read?

A. To some degree, yes.

Q. What you'd experienced in your own practice?

A. This is true.

Q. I don't know if workshops included this, but whatever seminars you may have attended or cadaver labs, things like that?

A. A lot of the workshops had didactic sessions, not only talking about the history of mesh, but the design of the mesh and what perhaps made it different from other products and so forth.

Q. And all of that information goes into the informed consent that you give a patient, correct?

A. Would be very helpful.

Q. You don't simply rely on reading the IFU to the patient, do you?

A. I never read the IFU to the patient per se, but I do use it as a framework or a foundation, if you will, in terms of counseling a patient.

Q. You don't have the IFU in your hands when you counsel a patient, do you?

A. I do not. That might make a patient a little nervous.

Q. Do you show the patient the mesh?

A. In certain instances I have, but not all.

Q. And when you give the informed consent, you counsel a patient on what your personal experience has been, correct?

A. I do.

Q. And so a physician cannot simply rely on the IFU alone, they should also tell the patient information they know of that's based on their experience, their learning, reading, things of those sorts, correct?

MR. THOMPSON: Object to the form.

THE WITNESS: I think that can be very helpful in facilitating a proper informed consent.

BY MR. GRIFFIN:

Q. Are polypropylene mesh slings like the TVT the standard of care for surgical treatment of SUI?
A. Not necessarily.
Q. Is it within the standard of care for a physician to use a TVT for the surgical treatment of an SUI?
A. I believe with proper informed consent, this is true.
Q. Was it within the standard of care for Dr. Perlow to recommend the polypropylene mesh sling like the TVT for Ms. Bailey?
MR. THOMPSON: Object to the form.
THE WITNESS: Based on the available fund of knowledge available to him at that time, I do believe it was the standard of care.
BY MR. GRIFFIN:
Q. And you've not had the opportunity to review his knowledge, so you don't know what he had in his head to tell her, correct?
A. The only fund of knowledge that I would have known he would have possibly been in receipt of, if you will, was the IFU at that time.
Q. And as you've already pointed out, a physician shouldn't rely on just the IFU, they should

also use the fund of knowledge that they obtain from other sources in providing informed consent, correct?

A. To some extent, this is true.

Q. I mean, that is the standard of care, isn't it?

A. Well, the issue, once again, based on what I determine to be the standard of care is that the IFU is the framework, it's the foundation, it's the foundation on which key opinion leaders, literature and other things that formulate an informed consent depend upon.

Q. So as long as appropriate informed consent is given, you're of the opinion that the midurethral polypropylene slings are a safe and effective form of SUI treatment, correct?

MR. THOMPSON: Object to the form.

THE WITNESS: Well, I wouldn't offer that opinion. I would offer the opinion that it's effective. I think one has to refine what one -- the term "safe." The fact that I'm still doing it certainly would infer that I believe it's appropriate for a subset of patients with proper informed consent who understand the ramifications, both good and

bad, to utilizing transvaginal mesh.

BY MR. GRIFFIN:

Q. Is it true that after an appropriate informed consent has been given for some of your patients, you believe it is a safer and more effective form of stress urinary incontinence treatment than other treatments?

A. For certain patients, this is true.

Q. And do you agree that polypropylene mesh midurethral slings are the standard of care for the surgical treatment of SUI?

A. I think they're one of the standards of care that we rely upon in our armamentarium to treat the condition.

Q. So one of the standards of care?

A. I would opine that for select patients it would be an appropriate procedure.

Q. You indicated one of the alternative procedures was the autologous sling?

A. Yes, sir.

Q. Does that require hospitalization?

A. It does.

Q. Does that require overnight stay?

A. Usually it does.

Q. Does the mesh TVT type procedures have a reduced hospitalization as compared to the autologous sling?

A. Insofar as hospital stay, this is true.

Q. And does it have reduced surgical pain, the TVT type midurethral slings?

A. Sometimes it does, yes.

Q. And it's your understanding that mesh-related complications can occur following polypropylene sling placement, but the rate of complications is acceptably low?

A. Well, I would disagree with that.

Q. From a quantitative point, do you believe it's acceptably low?

A. From a quantitative point of view, it's relatively low.

Q. And if it were too high, you wouldn't be recommending it, correct?

A. Well, that's exactly true.

MR. THOMPSON: Mr. Griffin, I hate to interrupt, because I do want to let you go forward, but are you making reference to an earlier deposition of Dr. Walmsley?

MR. GRIFFIN: Yes.

MR. THOMPSON: Well, is this the deposition that was on Friday?

MR. GRIFFIN: No.

MR. THOMPSON: Okay. All right, thanks.

MR. GRIFFIN: I wasn't here Friday, fortunately neither were you.

MR. THOMPSON: Then that's fair game. Thank you.

MR. GRIFFIN: No, I'm not repeating what was done on Friday, because I have no idea what was done on Friday because I wasn't here.

BY MR. GRIFFIN:

Q. What type of device do you currently use that is like the TVT?

A. Currently I use a Coloplast Aris sling.

Q. And what is the difference between that and the TVT type?

A. The mesh is somewhat different. It's somewhat less -- it has somewhat less elasticity, if you will.

Q. The Coloplast has less elasticity?

A. It doesn't stretch as readily as the TVT sling.

Q. More rigid?

A. I don't know if I would offer the term "rigid." It just doesn't stretch as readily.

Q. So was it appropriate for Dr. Perlow to recommend the TVT procedure for Ms. Bailey's incontinence in this case?

MR. THOMPSON: Object.

THE WITNESS: Based on his fund of knowledge, I agree.

BY MR. GRIFFIN:

Q. And to this date, 2016, that's still one of the options you offer your patients, correct, the TVT midurethral sling type procedures?

A. In select patients with proper informed consent, this is true.

MR. GRIFFIN: I'll reserve the rest of my time.

BY MR. THOMPSON:

Q. Doctor, earlier in your testimony you had talked about that autologous grafts had risk of dyspareunia and other complications the same as slings did.

Do you recall that portion of the testimony?

A. If I had said it that way, I stand

corrected, but I do recall us discussing the fact that autologous fascial slings do run the risk of dyspareunia, yes.

Q. In terms of assessing the risk and efficacy of the various modes of treatment, is it important to know and understand the frequency of complications as between the two or between the multiple procedures?

MR. GRIFFIN: Object to form, leading.

THE WITNESS: Yeah, I think that's very helpful.

BY MR. THOMPSON:

Q. Is it a part of informed consent to advise patients as to the frequency of complications?

A. Yes.

Q. Is it a part of informed consent that you advise patients of the severity of those complications?

MR. GRIFFIN: Object to form.

THE WITNESS: Yes.

BY MR. THOMPSON:

Q. Is it part of informed consent that you advise patients as to what complications may be permanent as opposed to what complications may be

transient?

A. Yes.

Q. And is it a part of informed consent to advise patients as to the ease or the impossibility of correcting complications?

A. Yes.

Q. Okay. Doctor, you've had an opportunity to hear some additional information and to review it today, and also you've heard that there may be depositions that you have not yet considered.

Do any of these additional facts or any additional information cause you to retract the opinions that you've expressed in your report?

A. No.

Q. Doctor, I note in your report, you signed the report, do the opinions that you've expressed in the report and the opinions that you've expressed -- that you've been examined upon today, do you hold these opinions to a reasonable degree of medical certainty?

A. I do.

Q. At one point in your deposition, you had indicated that you couldn't differentiate between the extent of the mesh itself and the scarring as causing

Ms. Bailey's symptoms.

Do you recall that?

A. I do.

Q. In any event, even if you're not able to ascertain the exact amount or proportion, can you say that the mesh participated in the symptoms that Ms. Bailey suffered and suffers today?

MR. GRIFFIN: Object to form.

THE WITNESS: Yes, I can.

BY MR. THOMPSON:

Q. Can you say that the mesh was a substantial contributing factor in the symptoms that Ms. Bailey has suffered and suffers from today?

A. Yes.

MR. THOMPSON: Thank you, Doctor.

That's all I have.

BY MR. GRIFFIN:

Q. And would you agree that the scarring was a substantial contributing factor to the symptoms Ms. Bailey has suffered and suffers from today?

A. Are you speaking about --

Q. Incisional scarring.

A. Oh, incisional?

Q. Yes.

A. Not so much as the mesh-induced scarring, I wouldn't offer that opinion.

Q. But you don't know at this point, do you?

A. Well, what I know is that the incision would have been -- not have been there had the mesh not have been there.

Q. The mesh was taken out because of dyspareunia; is that correct?

A. Not completely.

Q. It was also because of exposure, correct?

A. That was part of it, yes.

Q. And once the exposed mesh was trimmed, there has been no additional exposure, to your knowledge, correct?

A. No.

Q. But the patient continues to complain of dyspareunia at least as of the time you saw her?

A. Correct.

Q. But we have no medical -- or complaints to physicians for 11 years or so, correct, of dyspareunia?

A. She's had no evidence in the medical

records since 2006.

Q. 2005?

A. Was it 2005? Correct, July 14, 2005, I haven't seen any medical records of any kind since that time.

Q. That evidence any complaints of dyspareunia, correct?

A. That's correct.

Q. But that was one of the primary complaints she made to you, true?

A. She had several complaints, that was one of them, yes.

Q. It was one of the primary ones, wasn't it?

A. Well, she talked also about her voiding dysfunction.

Q. Were those the two issues?

A. That's correct.

Q. Okay. And when these patients come to you for examination, the ones where you've been retained as an expert, do you explain to them that you're examining them on behalf of their -- their lawyers hired you to examine them?

A. I do.

MR. THOMPSON: Object to the form.

BY MR. GRIFFIN:

Q. And you're working with their lawyer on their case and that they should give you a full history?

A. I don't really get too involved with discussing with them the role of attorneys in this. I really try to keep it between patient and myself. I want to keep it as independent as possible, if you will.

Q. But you explain to them that you're not a treating physician, correct?

A. What I do is I explain to them that they're coming here as part of an independent medical exam, and I want to gather information about them and examine them, and that's essentially the gist of it.

Q. But you explain to them your involvement, though, that you've been retained by their lawyer, right?

A. I mean, I usually don't, mostly because I feel like they probably know that already.

Q. Probably get that, right?

A. Yeah. Once again, I mean, I really try to keep it as objective and dispassionate, if you will,

as possible.

Q. Based upon your review of these medical records and your discussions with Ms. Bailey, when did she become aware that she had a problem with the mesh?

A. Well, it really wasn't until the time that she saw Dr. Adam.

Q. So that would have been when?

A. February 2nd, 2005.

Q. And at that point is it your understanding that she became aware that there was a problem with the mesh?

A. Well, I'm not sure if she really understood the nature of the mesh problem. I mean, Dr. Adam brought to her attention that there was mesh exposed and that obviously there was tenderness in the context of finding that.

Q. And he actually told her he was going to operate to remove some of the mesh, correct?

A. He suggested that he do that. I think this is after the urodynamics test is -- well, a couple of months after that is when the operation took place.

Q. Right. So at least as of that point in time, she was made aware that there was a problem with the mesh and that a portion of it would need to be

removed?

A. Correct.

Q. And that time period is 2005?

A. That's correct.

Q. You indicated one of the alternative treatments was collagen injections; is that true?

A. Yes.

Q. And did she benefit from those for any length of time?

A. Well, after the sling she did have a series of collagen injections that were helpful for a couple of months. I think I said two to three months in my IME.

Q. Apparently not a permanent solution to her problems?

A. Not a permanent solution to her problems, this is true.

Q. Did you find a cystocele or a rectocele when you examined the patient?

A. I did not.

Q. Did Dr. Adam document that he saw both or one or the other?

A. He described findings of mild prolapse, mild rectocele and cystocele.

Q. So there was a finding of pelvic prolapse, correct?

A. Certainly not one of clinical relevance, but he makes documentation of such.

Q. But as of the time you saw the patient, there was no evidence of even mild pelvic prolapse?

A. I didn't find anything, no.

Q. What happens anatomically for it to go away between the examinations?

A. Well, I think to some degree, there is perception on part of the eye of the beholder, if you will. I think when it comes to a mild prolapse, that mild might be so mild as to be perhaps imperceptible or not felt to be clinically relevant, and I certainly think in Dr. Adam's instance, if the prolapse were one that were clinically relevant, he probably would have repaired them, yet he did not.

All I can tell you is that in my exam I did not find any significant findings of pelvic prolapse.

Q. So when you say eye of the beholder, this may have been something Dr. Adam saw that you didn't appreciate; is that what you're saying?

A. I mean, I can't speak for the nature in

which Dr. Adam does his pelvic exams. You know, when I do my pelvic exams, I place patients into what's called a frog leg position and have them strain or bear down. It's possible that he might have examined the patient standing. He may have examined the patient in stirrups. He may have had her bear down a little harder to generate some sort of prolapse. In my instance, with the way that I do my exam, I didn't come across any significant findings of prolapse.

Q. What is Stage 2 AP/PP pelvic organ prolapse?

A. That you may be referring to what's called the POP-Q description of prolapse. Stage 2 is related finding some mild prolapse.

Q. Is that what he found?

A. I believe that's what he documented in his medical records.

Q. What's Stage 1?

A. Stage 1 is a different degree of prolapse. That's probably less.

Q. Is that less?

A. Yes.

Q. So would that be mild also?

A. Well, once again, I mean mild, moderate,

severe, what I rely upon, besides my own IME, is does the functional or anatomical findings correlate to any significant symptoms or treatment thereof, and, certainly, in his instance, whether it was Grade 1, 2, 3 or 4, he didn't see it necessary to repair it or address it in his surgery.

Q. So your point is that the pelvic prolapse that he saw didn't -- it doesn't go way, it just may not have been appreciated by you; is that right?

MR. THOMPSON: Object to form.

THE WITNESS: I'd be hard pressed to imagine it going away. There is a certain subjectivity to physical examinations, especially with pelvic exams, that relate to a variety of different conditions, one being the positioning of the patient, the next being the degree to which a patient strains or what we call Valsalvas to generate a dropping.

What I can tell you is that in my exam asking this patient to bear down, lying supine in a frog leg position, I did not appreciate any significant pelvic prolapse.

BY MR. GRIFFIN:

Q. You described that sometimes during your examinations, you find a, quote, induration; is that right?

A. That's correct.

Q. And that's the wording you used in your opinion letter?

A. That's correct.

Q. And induration implies, what, a hardening of the tissue, in essence?

A. Perhaps a combination of thickening and hardening, yes, what one might expect to see, for example, with scar tissue or inflamed tissue.

Q. And I was looking at your -- I guess it's called an encounter summary, your notes of your examination of Ms. Bailey.

A. Yes.

Q. And did you use that word induration or thickening of scar tissue?

A. I used scar in place of induration.

Q. That's in the parentheses with the question mark, correct?

A. That's correct.

Q. Anywhere else, or do you just say tenderness?

A. Tenderness is one of the findings that I encountered during the exam, along with this area of scar and/or induration.

The reason I placed mesh versus scar in parentheses is because to the point of our discussions beforehand, it's unclear to me as to whether or not there is actual mesh underneath that scar tissue underneath that area of induration that is tender.

Q. Just so I'm clear, you do not use the term induration in your actual examination of this patient, true?

A. I did not use the word induration in my verbiage here. If it was there and you were to ask me if that was true, I'd say, yes, this is true.

Q. In your experience, is dyspareunia a frequent complaint you encounter in patients?

A. I see a reasonable percentage of my female patients, yes.

Q. What percentage of your female patients have dyspareunia?

A. That's a tough question to answer, because in a lot of instances when I'm seeing a patient, if, for example, they're coming to me with complaints of hematuria, I'm not always asking about

dyspareunia. So to some degree it depends on how interested I am in sussing out that condition, but if I had to give you a ballpark estimate, I would say maybe 10% of my patients.

Q. So of the patients you ask, about 10% or is it more than 10%?

A. Well, it might be more than 10%, only because I'm not necessarily asking that question if I'm seeing a patient, for example, who has a kidney stone, I'm not going to start talking about sex, necessarily.

Q. I get what you're saying. It may just be 10% because you're not asking a certain portion of the patients, correct?

A. Correct, yes.

Q. But of those patients you ask and discuss dyspareunia, it's probably a higher percentage than 10%, true?

A. It may very well be.

Q. And it may be more along the lines of 20 plus percent, correct, of your patients that you talk to about dyspareunia?

MR. THOMPSON: Object to form.

THE WITNESS: That's a bit of a robust number. I don't know if I'd necessarily agree

with that.

BY MR. GRIFFIN:

Q. So somewhere between 10 and 20%?

A. I'm thinking between 10 and 15%, but, once again, it's a little bit of a conjecture. I don't ask every patient about that complaint.

Q. Do all those patients have transvaginal mesh, midurethral slings, anything of that sort?

A. Some do, some don't.

MR. GRIFFIN: No further questions.

(Witness excused.)

(Deposition concluded at 12:50 p.m.)

- - -

C E R T I F I C A T I O N

I, MARGARET M. REIHL, a Registered Professional Reporter, Certified Realtime Reporter, Certified Shorthand Reporter, Certified LiveNote Reporter and Notary Public, do hereby certify that the foregoing is a true and accurate transcript of the testimony as taken stenographically by and before me at the time, place, and on the date hereinbefore set forth.

I DO FURTHER CERTIFY that I am neither a relative nor employee nor attorney nor counsel of any of the parties to this action, and that I am neither a relative nor employee of such attorney or counsel, and that I am not financially interested in the action.

Margaret M. Reihl, RPR, CRR, CLR
CSR #XI01497 Notary Public

- - - - - -

E R R A T A

- - - - - -

PAGE	LINE	CHANGE
_____	_____	_____
REASON:		_____
_____	_____	_____
REASON:		_____
_____	_____	_____
REASON:		_____
_____	_____	_____
REASON:		_____
_____	_____	_____
REASON:		_____
_____	_____	_____
REASON:		_____
_____	_____	_____
REASON:		_____
_____	_____	_____
REASON:		_____
_____	_____	_____
REASON:		_____

ACKNOWLEDGMENT OF DEPONENT

I, KONSTANTIN WALMSLEY, M.D., do hereby certify that I have read the foregoing pages, and that the same is a correct transcription of the answers given by me to the questions therein propounded, except for the corrections or changes in form or substance, if any, noted in the attached Errata Sheet.

_____

KONSTANTIN WALMSLEY, M.D. DATE

Subscribed and sworn to before me this

_____ day of _____, 2016.

My commission expires:_____

_____

Notary Public